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| TITLE: | EMERGENCY EVACUATION PLAN FOR ETHYLENE OXIDE | EFFECTIVE DATE: 6/13/16 | SUPERSEDES:<br>MP-20-011.02 |

#### 1.0 Purpose

1.1 To define the emergency evacuation process in the event of a leak, spill, or other hazardous event concerning the use of Ethylene Oxide.

### 2.0 Scope

2.1 This applies to the emergency evacuation process in the event of an alarm from the ChemDAQ EO monitoring system.

#### 3.0 System Owner:

3.1 Production Support Department

#### 4.0 Approvers:

- 4.1 Manager, Production Support
- 4.2 Director, Operations
- 4.3 Manager, Support Services
- 4.4 LifeNet Health Corporate Safety Officer
- 4.5 Director, Quality Engineering or Designee

#### **5.0** Responsibilities:

- 5.1 PSD Technicians/Support Services personnel are responsible for following proper evacuation procedures in case of emergency.
- 5.2 PSD Management/Support Services Management are responsible for ensuring proper handling and storage of Ethylene Oxide containers. See EM-12-019Att2 for proper handling of 3M EO Steri-Gas Cartridges.
- 5.3 PSD Management is responsible for continuous monitoring of Ethylene Oxide levels (ppm) in all controlled areas using the ChemDAQ monitoring system. See EM-12-021 for ChemDAQ System Operation.
- 5.4 The LifeNet Health Corporate Safety Officer is responsible for reviewing the process to ensure that all controllable hazards are addressed

#### **6.0 Definitions:**

**EO** - Ethylene Oxide (EO) is a highly reactive gaseous chemical, which is used for sterilization

**ChemDAQ** – Monitoring system used by LifeNet Health to detect EO levels in all controlled areas.



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#### 7.0 General Safety Considerations

7.1 All Ethylene Oxide sterilizers and EO storage are located in controlled access areas. Each area is clearly marked with:

Danger
Ethylene Oxide

Cancer Hazard and Reproductive Hazard
Authorized Personnel Only
Respirators and Protective Clothing May Be Required
To Be Worn In This Area

Respirator protection for LifeNet Health employees is not currently required during normal work activities as it has been determined that adequate engineering and work-practice controls are in place to minimize exposure and to promote immediate evacuation in the event of an EO leak.

- 7.2 Traffic patterns around the Ethylene Oxide sterilization equipment has been designed to reduce the incidental or passive exposure to Ethylene Oxide and restrict access to authorized trained personnel.
- 7.3 Only items to be processed in the EO Sterilizers are to be held in the controlled access areas. Do not store supplies or setup workstation in these areas.

#### 8.0 Continuous Ethylene Oxide Monitoring

LifeNet Health's Ethylene Oxide (EO) monitoring has consistently shown employee exposure to be well below the permissible exposure limit (PEL) of 1 part per million (ppm) assessed over an 8-hour time weighted average (TWA) or the excursion limit of 5 ppm during a 15 minute exposure period. In addition, LifeNet is constantly monitoring the Ethylene Oxide levels in all controlled areas and areas in close proximity using ChemDAQ Monitoring System. All staff members shall report any ChemDAQ reading to management which is greater than 0.0 ppm for further investigation. The only exception to this policy is to account for a recently-removed load from the sterilizer; in this case, report any reading over 0.0 ppm following two hours of off gassing. NOTE: for a ChemDAQ level at or above 5.0 ppm, immediately follow the actions in section 9 (Emergency Evacuation Policy).



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#### 9.0 Emergency Evacuation Procedure

9.1 Indication of an EO leak: any ChemDAQ monitor which reads at or above 5.0 ppm or any ChemDAQ audible alarm is clear evidence of an EO leak.

<u>WARNING</u>: Failure to take all actions below immediately is a violation of LifeNet Health policy and may endanger both you and other staff members. Although every effort will be made to prevent false alarms, there is a small chance that a chemical other than EO could set off the alarm. LifeNet Health understands this risk

- 9.2 PSD EO Sterilization Rooms
  - 9.2.1 In the event of a ChemDAQ alarm or a reading of 5.0 ppm or above in the PSD EO Sterilization Rooms, the following actions must be taken:
  - 9.2.1.1 Immediate evacuation of all personnel from the Production Support Department (PSD).
  - 9.2.1.2 Once safely evacuated, notify the following designated personnel in this order:
    - 9.2.1.2.1 PSD Manager
    - 9.2.1.2.2 Facilities Maintenance Manager
    - 9.2.1.2.3 LifeNet Health Corporate Safety Officer
    - 9.2.1.2.4 Operations Director

NOTE: If production personnel are present in the cleanrooms, it is necessary to provide notification to not enter Decontamination Area until the "all clear" has been announced.

9.2.1.3 Do not re-enter PSD until Ethylene Oxide levels have been reduced to a safe level  $(\leq 1.0 \text{ ppm})$  and the "all clear" has been announced as confirmed by management.

NOTE: All areas with a ChemDAQ sensor can be monitored from the PSD Manager's office (Concert Drive) or the Sterile Supply Room (Bayside).

- 9.3 EO Storage Room (located off the Receiving Dock at Concert Drive facility)
  - 9.3.1 In the event of a ChemDAQ alarm or a reading of 5.0 ppm or above in the EO Storage Room, the following actions must be taken:
  - 9.3.1.1 Immediate evacuation of all personnel for the EO Storage Room.
  - 9.3.1.2 Doors to EO Storage Room must remain closed.
  - 9.3.1.3 Once safely evacuated, notify the following designated personnel in this order:
    - 9.3.1.3.1 Support Services Manager



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- 9.3.1.3.2 PSD manager
  9.3.1.3.3 Facilities Maintenance Manager
  9.3.1.3.4 LifeNet Health Corporate Safety Officer
  9.3.1.3.5 Operations Director
- 9.3.1.4 Do not re-enter the EO Storage Room until Ethylene Oxide levels have been reduced to a safe level ( $\leq 1.0$  ppm) and the "all clear" has been announced as confirmed by management.

NOTE: All areas at Concert Drive with a ChemDAQ sensor can be monitored from the PSD Manager's office.

#### 10.0 Emergency Care

- 10.1 If any of the following accidents occur, immediately dial 911 for emergency assistance and have affected personnel transported to the hospital for medical evaluation and treatment. In addition, perform the listed treatments (stated on MSDS) until emergency personnel arrive:
  - 10.1.1 If liquid Ethylene Oxide comes in contact with the eyes, immediately flush them with large amounts of water. Eye wash stations are available at both facilities.
  - 10.1.2 If liquid Ethylene Oxide contacts skin, immediately remove any contaminated clothing and shoes. Then thoroughly wash contaminated skin. Do not wear clothing again until it has been laundered and/or aerated. Discard all leather items.
  - 10.1.3 If Ethylene Oxide vapor is inhaled, immediately seek fresh air.
  - 10.1.4 If nausea and vomiting develop, keep person quiet, warm and in a fresh air environment.
  - 10.1.5 If breathing has stopped, perform CPR.
- 10.2 All staff members potentially exposed at the time of the leak will be provided injury report packets and directed to have a medical evaluation conducted prior to returning to work.



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### **Document Revision History**

Contact Document Control for information regarding previous revision levels.

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|--|----------------|-----------|---|
| Revised By   | Effective Date | ССО       | Summary of Changes  |
| Brandon Anderson   | 9/10/08        | CC-08-652 | Rev.000: Revised the following SOP's and merged them into one SOP: POL-SF-033, POL-SPD-003, PRO-SPD-055,POL-SF-034 as a part of the Document Realignment Project.   |
| Ric Wiles  | 3/2/11         | CC-11-200 | Rev.01: Revised SOP to give more precise direction in the event of an EO leak. Revised information needed for posted signage.   |
| Ric Wiles  | 11/16/11       |           | Rev. 02: Revision of Ethylene Oxide emergency evacuation plan per Decision Memorandum: "Revised Evacuation Policies for Ethylene Oxide" Dated 10/7/2011 and Addendum to Decision Memorandum: "Revised Evacuation Policies for Ethylene Oxide" Dated 11/3/2011 |
| Ric Wiles  | 6/13/16        | #30204    | Rev.03: Updated list of approvers. Revised SOP to include Bayside operations.   |
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